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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,187	08/21/2003	Emilio A. Emini	21390	7065

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EXAMINER	
WHITEMAN, BRIAN A	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 09/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,187	EMINI ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,25-36* is/are pending in the application.

4a) Of the above claim(s) *18,19,21,31-33,35,36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,20,25-30 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/4/05,7/8/04,4/1/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Non-Final Rejection

Claims 1-21 and 25-36 are pending.

The amendment to claims 18 and 31 and the cancellation of claims 22-24 in the paper filed on 9/6/05 is acknowledged and considered by the examiner.

Election/Restrictions

Applicant's election with traverse of Group I and species HIV-gag in the reply filed on 9/6/05 is acknowledged. The traversal is on the ground(s) that it should not be an undue burden for the examiner to evaluate Applicant's specification in its entirety and the election of species is traversed. This is not found persuasive because the examiner has set forth in the election/restriction mailed on 8/5/05 for why it would be an undue burden on the examiner and the applicant has not addressed these reasons of record for an undue burden. The election of species is not found persuasive because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has been treated as an election of species without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 18, 19, 21, and 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and Claims 35 and 36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/6/05.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 5/4/05, 7/8/04, and 4/1/04 is being considered by the examiner.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bout et al. (20050084480). Bout teaches a recombinant adenovirus comprising a gene of interest, wherein the adenovirus is from serotype 34, cells comprising the adenovirus and methods of producing the adenovirus (pages 65-66). Bout further teaches that the adenovirus has a deletion in the E1 region and is devoid of E1 activity (pages 65-66). Bout teaches a pharmaceutical composition comprising the adenovirus (page 65).

Claims 1-17, 20, 25-30, and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by Bett et al. (US 20040106194).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C.

102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Bett teaches a recombinant adenovirus comprising a gene of interest (HIV Gag gene), wherein the adenovirus is from serotype 34, cells comprising the adenovirus and methods of producing the adenovirus (pages 2, 4-5, 16-18, and 69-71). Bout further teaches that the adenovirus has a deletion in the E1 region and is devoid of E1 activity (pages 67-71). Bout teaches a pharmaceutical composition comprising the adenovirus (page 71).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16, 20, 25-30 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bout et al. (20050084480) taken with Chen et al (WO 01/02607, cited on an IDS). Bout teaches a recombinant adenovirus comprising a gene of interest, wherein the adenovirus is from serotype 34, cells comprising the adenovirus and methods of producing the adenovirus (pages 65-66). The adenovirus is not associated with severe human pathology in immunocompetent individuals (page 1). The virus is extremely efficient in introducing its DNA into a host cell; the virus can infect a wide variety of cells and has a broad host-range (page 1). The virus can be produced at high virus titers in large quantities (page 1). The virus can be rendered replication defective by deletion of the early-region 1 (E1) of the viral genome (page 1). Most adenoviral vectors currently used in gene therapy have a deletion in the E1 region, where desired genetic information can be substituted (page 1). The vast majority of people have had previous exposure to adenoviruses, especially the well-investigated adenovirus serotypes 5 and type 2 (page 1). Bout teaches that the number of individuals with neutralizing antibody titers to the serotypes 26, 34 and 48 was very low (page 8). Therefore, recombinant E1-deleted adenoviruses based on one of the other above mentioned serotypes have an important advantage compared to recombinant

vectors based on Ad5 with respect to clearance of the viruses by neutralizing antibodies (page 8). Bout further teaches that the adenovirus has a deletion in the E1 region and is devoid of E1 activity (pages 65-66). Bout teaches a pharmaceutical composition comprising the adenovirus (page 65). However, Bout does not specifically teach using an HIV gene as the gene of interest.

However, at the time the invention was made, Chen teaches an adenovirus carrying an HIV-1 gag gene, wherein the gene is codon-optimized gag gene for expression in humans (abstract and page 1).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Bout taken with Chen, namely to produce a recombinant adenovirus comprising a HIV gene, wherein the HIV gene encodes HIV-1 gag. One of ordinary skill in the art would have been motivated to combine the teachings because adenovirus serotype 34 has a low neutralizing antibody in vivo compared to adenovirus serotype 2 or 5.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Bout taken with Chen, namely to use a method to produce the recombinant replication defective adenovirus comprising a HIV gene, wherein the HIV gene encodes HIV-1 gag. One of ordinary skill in the art would have been motivated to combine the teachings because in order to produce replication defective adenovirus particles the method of production is required.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17, 20, 25-30, and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 71-76, 79, and 81 of copending Application No. 10/645,794. Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are directed to an adenovirus serotype 34 vector which is at least partially deleted in E1 and devoid of E1 activity, wherein the vector comprises a heterologous gene encoding an HIV-gag polypeptide.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-17, 20, 25-30, and 34 are directed to an invention not patentably distinct from claims 71-76, 79, and 81 of commonly assigned US application 10/645,794. Specifically, for the reasons set forth under the double patenting rejection.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned US application, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, acting SPE – Art Unit 1635, can be reached at (571) 272-0811.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635